IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
HETERO USA INC. and HETERO LABS LIMITED,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff AbbVie Inc., by way of Complaint against Hetero USA Inc. and Hetero Labs Limited, states as follows:

THE PARTIES

1. Plaintiff AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global biopharmaceutical company engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. On information and belief, Defendant Hetero USA Inc. ("Hetero USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854, and is registered to do business in Delaware, including its appointment of a registered agent in Delaware (located at W/K Incorporating Services, Inc., 3500 South Dupont Highway, Dover, DE 19901) for the receipt of service of process.

3. On information and belief, Defendant Hetero Labs Limited ("Hetero Labs") is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar Hyderabad – 500 018 Andhra Pradesh, India.

4. On information and belief, Hetero Labs is a parent corporation of Hetero USA.

5. On information and belief, Hetero USA acts as the agent of Hetero Labs.

6. On information and belief, Hetero Labs and Hetero USA manufacture and sell various generic drug products and regularly conduct business throughout the United States, including in the State of Delaware.

NATURE OF THE ACTION

7. This is a civil action for patent infringement of United States Patent Number 7,148,359 B2 ("the '359 patent"), United States Patent Number 7,364,752 B1 ("the '752 patent"), United States Patent No. 8,268,349 B2 ("the '349 patent"), United States Patent No. 6,037,157 ("the '157 patent"), and United States Patent No. 6,703,403 B2 ("the '403 patent"), arising under the United States Patent Laws, Title 35, United States Code, §100, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 204587, which Hetero USA and Hetero Labs filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market a generic copy of AbbVie's successful Norvir® tablets that are sold in the United States, and which Hetero USA and Hetero Labs subsequently amended.

JURISDICTION AND VENUE

8. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment

Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Hetero USA and Hetero Labs.

10. Hetero USA and Hetero Labs have admitted that this Court has jurisdiction over them in *Forest Laboratories, Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, C.A. No. 12-305.

11. On information and belief, Hetero USA and Hetero Labs have availed themselves of this forum previously for the purpose of litigating a patent dispute. For example, Hetero USA and Hetero Labs have filed counterclaims for declaratory judgment.

12. On information and belief, Hetero USA is a Delaware corporation, is registered to do business in Delaware, and is the U.S. regulatory agent for Hetero Labs Limited Unit III.

13. On information and belief, Hetero Labs Limited Unit III is a division or part of Hetero Labs Ltd. Hetero Labs' website, located at http://www.heterodrugs.com/mfg-API-facilities.shtml, describes Unit III as an API manufacturing facility of Hetero Labs.

14. On information and belief, Hetero USA is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Hetero USA, either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware. On information and belief, the acts of Hetero USA complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Hetero Labs. In letters dated March 29, 2013 and April 1, 2013 notifying AbbVie of the submission to the FDA of Hetero's ANDA No. 204587, Hetero USA described itself as "the U.S. Regulatory Agent for Hetero Labs Limited Unit III."

15. On information and belief, this court has personal jurisdiction over Hetero USA by virtue of, *inter alia*: (1) its incorporation in the State of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware for the receipt of service of process; (3) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware; (4) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (5) its admission that it is subject to the Court's jurisdiction.

16. On information and belief, Hetero Labs formulates, develops, markets, and sells active pharmaceutical ingredients ("API"), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such API or pharmaceutical formulations (collectively "Hetero's products"). Hetero Labs, through its U.S. regulatory agent, Hetero USA, routinely files ANDAs seeking FDA approval to market its products in the United States.

17. On information and belief, Hetero Labs, directly or through Hetero USA and/or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Hetero Labs, either directly or through Hetero USA and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

18. Hetero USA's acts and continuous and systematic contacts with the State of Delaware, as an agent of Hetero Labs, are also attributable to Hetero Labs for jurisdictional purposes.

19. On information and belief, Hetero USA and Hetero Labs operate as an integrated business ultimately controlled by Hetero Labs.

20. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of FDA approval of Hetero's ANDA No. 204587, which is the subject of this lawsuit.

21. On information and belief, this Court has personal jurisdiction over Hetero Labs by virtue of, *inter alia*: (1) its presence in Delaware, including through Hetero USA; (2) its course of conduct that is designed to cause the performance of tortious acts that will result in the foreseeable harm in Delaware; (3) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (4) its admission that it is subject to the Court's jurisdiction.

22. Hetero USA and Hetero Labs hereinafter are referred to collectively as "Hetero."

23. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

24. AbbVie is the holder of approved New Drug Application ("NDA") No. 22-417 for ritonavir tablets, which AbbVie markets and sells under the trademark Norvir®. AbbVie manufactures and sells Norvir® 100 mg tablets in the United States under NDA No. 22-417.

25. Hetero filed with the FDA ANDA No. 204587 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market ritonavir tablets 100 mg ("Hetero Labs' generic ritonavir tablets"), which are generic copies of AbbVie Norvir® tablets.

26. Upon information and belief, ANDA No. 204587 seeks FDA approval of a pharmaceutical composition comprising ritonavir in a 100 mg dosage strength.

27. Upon information and belief, ANDA No. 204587 seeks FDA approval to market generic ritonavir tablets in the United States.

28. On April 2, 2013, AbbVie and Abbott Laboratories ("Abbott") received a letter on behalf of Hetero, dated March 29, 2013, purporting to be a "Notification Pursuant to Section 505(j)(2)(B) [21 USC § 355(b)(4)(B)]" for ANDA No. 204587 pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95(e). Hetero's March 29, 2013 Notice Letter notified AbbVie and Abbott that Hetero had filed ANDA No. 204587, seeking approval to market generic ritonavir tablets prior to the expiration of the '359, '752 and '349 patents.

29. On April 2, 2013, AbbVie and Abbott received a letter on behalf of Hetero, dated April 1, 2013, purporting to be a "Notification Pursuant to § 505(j)(2)(B)(ii) [21 USC § 355(j)(2)(B)(ii)]" for ANDA No. 204587 pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95(e). Hetero's April 1, 2013 Notice Letter notified AbbVie and Abbott that Hetero had amended ANDA No. 204587, seeking approval to market generic ritonavir tablets prior to the expiration of the '157 patent and the '403 patent.

THE PATENTS-IN-SUIT

30. The '359 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on December 12, 2006. AbbVie is the owner by assignment of the '359 patent and has the right to sue for infringement thereof. AbbVie lists the '359 patent in the Orange Book for NDA No. 22-417. The '359 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the '359 patent is attached as Exhibit A.

31. The '752 patent was duly and legally issued by the PTO on April 29, 2008. AbbVie is the owner by assignment of the '752 patent and has the right to sue for infringement

thereof. AbbVie lists the '752 patent in the Orange Book for NDA No. 22-417. The '752 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the '752 patent is attached as Exhibit B.

32. The '349 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on September 18, 2012. AbbVie is the owner by assignment of the '349 patent and has the right to sue for infringement thereof. AbbVie lists the '349 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 22-417. A true and correct copy of the '349 patent is attached as Exhibit C.

33. The '157 patent was duly and legally issued by the PTO on March 14, 2000. AbbVie is the owner by assignment of the '157 patent and has the right to sue for infringement thereof. AbbVie lists the '157 patent in the Orange Book for NDA No. 22-417. The '157 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the '157 patent is attached as Exhibit D. On May 8, 2013, the PTO issued a Notice of Intent to Issue a Reexamination Certificate. (Ex. E; Notice of Intent to Issue Ex Parte Reexamination Certificate.)

34. The '403 patent was duly and legally issued by the PTO on March 9, 2004. AbbVie is the owner by assignment of the '403 patent and has the right to sue for infringement thereof. AbbVie lists the '403 patent in the Orange Book for NDA No. 22-417. The '403 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the '403 patent is attached as Exhibit F.

35. In October 2011, Abbott announced that it planned to separate into two independent, publicly traded companies, one in medical products and the other in research-based pharmaceuticals. On January 1, 2013, Abbott completed the separation of its research-based

pharmaceuticals business, which became AbbVie. AbbVie was incorporated in Delaware on April 10, 2012.

36. As a result of the separation, Abbott is neither the holder of NDA No. 22-417 nor patent owner of the '359 patent, the '752 patent, the '349 patent, the '157 patent or the '403 patent.

FACTS PERTINENT TO THE CLAIMS

37. Infection by the virus known as "HIV," or human immunodeficiency virus, is a serious health problem affecting millions of patients around the globe. Norvir® tablets, sold by AbbVie throughout the United States, is a critical component of HIV treatment for many patients. Norvir® is approved for use in combination with other anti-retroviral agents for the treatment of HIV-1 infection. (Ex. G; Norvir® Labeling at Section 1, Indications and Usage.)

38. Abbott researchers, some of whom are now AbbVie researchers, made the unexpected discovery that ritonavir, the active ingredient in Norvir®, is capable of boosting the effectiveness of other HIV treatments, including drugs known as "protease inhibitors." Ritonavir accomplishes this feat by inhibiting a certain enzyme, known as "cytochrome P450 monooxygenase" ("CYP"), that normally metabolizes protease inhibitors, leading to the need for more frequent and higher doses than desired. This groundbreaking discovery transformed the treatment of HIV infections, allowing for the use of potent protease inhibitors at lower doses, and consequently fewer attendant side effects, when administered with ritonavir. This discovery was not the mere coadministration of ritonavir with a companion drug but rather was that the ritonavir and/or the companion drug could be administered in lower amounts which were previously understood to be ineffective. This unique innovation ushered in a new era in the treatment of HIV/AIDS.

39. In fact, there are several known AIDS ("Acquired Immune Deficiency Syndrome") drugs that are not approved for monotherapy but that are approved for administration with ritonavir. The reason is because these other HIV drugs would be toxic in dosage amounts necessary for them to be effective for the treatment of AIDS when used alone. Ritonavir, however, allows them to be administered in lower amounts that are safe and translate into effective levels in the bloodstream. This is due to ritonavir's remarkable ability to inhibit CYP and thereby allow for the other HIV agent to be available in the bloodstream in effective amounts. This discovery has been a breakthrough in AIDS treatment.

40. The importance of ritonavir did not go unnoticed. In 1997, Dale Kempf, Daniel Norbeck, Hing Sham, and Chen Zhao of Abbott were awarded the 1997 National Inventor of the Year Award by the Intellectual Property Owners Association for their invention of Norvir®. (Ex. H.) Since 1974, this award has been given to distinguished inventors who have benefited the nation's economy and made a significant impact on society. According to IPO, the criteria used to judge the nominated candidates for the award include originality of concept, ingenuity in bringing the concept to market, societal benefit and commercial success. This award was followed in 1999 by the Pharmaceutical Research and Manufacturers of America's presentation of the Discoverers Award to Dale Kempf and Daniel Norbeck for their efforts in developing Norvir® and helping save the lives of AIDS patients. (Ex. I.) In addition, these Abbott chemists were also awarded the 2002 Industrial Innovation Award from the American Chemical Society for discovering the pioneering boosting effect of ritonavir. (Ex. J.)

41. The '157 patent claims, *inter alia*, methods of improving the pharmacokinetics of a drug that is metabolized by CYP comprising administering to a human in need of treatment of a therapeutically effective amount of a combination of the drug and ritonavir. The '403 patent

claims, *inter alia*, methods of improving the pharmacokinetics of a drug that is metabolized by CYP comprising co-administering to a human being treated with the drug and an amount of ritonavir effective to inhibit CYP. Thus, the patents claim the administration of ritonavir to patients suffering from HIV infection in combination with other anti-retroviral agents.

42. The specifications of the '157 and '403 patents disclose co-administration of ritonavir with a drug that is metabolized by CYP, for example, HIV protease inhibitors, in order to improve the pharmacokinetics of the drug and thus provide a useful treatment for HIV infection or AIDS in humans. (*E.g.*, '157 patent, col. 1, l. 49 – col. 2, l. 52; '403 patent, col. 1, l. 53 – col. 2, l. 52.) The '157 and '403 patents further disclose that ritonavir improves such drug's pharmacokinetics by inhibiting CYP. (*E.g.*, '157 patent, col. 1, l. 49 – col. 2, l. 52; '403 patent, col. 1, l. 53 – col. 2, l. 52.) This effect is reflected in the Norvir® labeling, which not only directs the use of Norvir® in combination with other anti-retroviral agents for the treatment of HIV-1 infection, but also describes ritonavir as an inhibitor of CYP, including cytochrome P450 3A ("CYP3A"), and discloses ritonavir's effect on various protease inhibitors. For example, the Norvir® labeling states that taking Norvir® may lead to increased plasma concentrations of concomitant medications, and that higher plasma concentrations can result in increased or prolonged therapeutic or adverse effects. (Ex. G at Section 5.1.) The Norvir® labeling further directs prescribers to refer to the full prescribing information of other protease inhibitors for details on co-administration. (Ex. G at Section 7.)

43. For example, the Norvir® labeling directs prescribers to the Prezista® (darunavir) labeling for details on co-administration of ritonavir and darunavir. (Ex. G at Section 7.) The Prezista® label, which states that darunavir must be administered with ritonavir and other anti-retroviral agents, also describes ritonavir's favorable pharmacokinetics effect. (Ex. K at Section

1.) The Prezista® labeling specifically states that Prezista® must be co-administered with ritonavir to exert its therapeutic effect and warns that failure to correctly co-administer darunavir with ritonavir results in insufficient plasma levels of darunavir. (Ex. K at Section 2.)

44. The Norvir® labeling similarly directs prescribers to consult labeling for other anti-retroviral agents, including Reyataz® (atazanavir), Lexiva® (fosamprenavir), indinavir, Invirase® (saquinavir), and Aptivus® (tipranavir) when co-administered with ritonavir. (Ex. G at Section 7.)

45. Based on the Norvir® labeling, physicians and healthcare professionals prescribing and administering ritonavir to treat HIV-1 infection understand and intend that ritonavir, when co-administered with certain drugs, like darunavir, improves the pharmacokinetics of the co-administered drug, thereby requiring a reduced dosage relative to that which would be necessary if administered without ritonavir.

46. Upon information and belief, Hetero has copied, and includes in its own proposed labeling for its proposed generic ritonavir tablets, the above-mentioned portions of the Norvir® FDA-approved labeling. Thus, upon information and belief, Hetero's proposed drug labeling contains descriptions indicating ritonavir's use in combination with other anti-retroviral agents for the treatment of HIV-1 infection. Therefore, the proposed products and labeling in ANDA No. 204587, if approved and marketed in the United States, would result in Hetero knowingly and intentionally encouraging, promoting, and inducing infringement of the AbbVie's patents-in-suit.

FIRST COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 7,148,359 B2

47. Paragraphs 1-46 are incorporated herein by reference.

48. On information and belief, Hetero USA, on behalf of Hetero Labs, filed ANDA No. 204587 in order to obtain approval to market generic ritonavir tablets in the United States before the expiration of the '359 patent. On information and belief, ANDA No. 204587 identifies Hetero Labs as the manufacturer of the generic ritonavir tablets. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 patent are purportedly invalid and/or not infringed.

49. On information and belief, Hetero USA and Hetero Labs acted in concert to seek FDA regulatory approval for generic ritonavir tablets manufactured by Hetero Labs. On information and belief, Hetero Labs actively and knowingly aided and abetted Hetero USA in the filing of ANDA No. 204587.

50. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204587 seeking approval for the commercial marketing of Hetero Labs' generic ritonavir tablets before the expiration date of the '359 patent constitutes infringement of one or more claims of the '359 patent, either literally or under the doctrine of equivalents.

51. Hetero Labs' inducement of Hetero USA to file ANDA No. 204587 constitutes infringement under § 271(b).

52. On information and belief, under § 271(b), Hetero Labs has knowingly and actively induced and specifically intended the acts of Hetero USA that will constitute direct infringement upon approval of ANDA No. 204587.

53. On information and belief, under § 271(b), Hetero USA has knowingly and actively induced and specifically intended the acts of Hetero Labs that will constitute direct infringement upon approval of ANDA No. 204587.

54. Upon FDA approval of ANDA No. 204587, Hetero USA and Hetero Labs will each infringe one or more claims of the '359 patent, either literally or under the doctrine of equivalents, under § 271(a) by making, using, offering to sell, selling, and/or importing generic ritonavir tablets, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 204587 shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity.

55. On information and belief, Hetero USA and Hetero Labs are aware and/or have knowledge that healthcare professionals and/or patients will use their generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the '359 patent.

56. The offering to sell, sale, making, and/or importation of generic ritonavir tablets would actively induce infringement of at least one of the claims of the '359 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of AbbVie's '359 patent, as evidenced by Hetero's March 29, 2013 Notice Letter.

57. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '359 patent. Pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 7,364,752 B1

58. Paragraphs 1-57 are incorporated herein by reference.

59. On information and belief, Hetero USA, on behalf of Hetero Labs, filed ANDA No. 204587 in order to obtain approval to market generic ritonavir tablets in the United States before the expiration of the '752 patent. On information and belief, ANDA No. 204587

identifies Hetero Labs as the manufacturer of the generic ritonavir tablets. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '752 patent are purportedly invalid and/or not infringed.

60. On information and belief, Hetero USA and Hetero Labs acted in concert to seek FDA regulatory approval for generic ritonavir tablets manufactured by Hetero Labs. On information and belief, Hetero Labs actively and knowingly aided and abetted Hetero USA in the filing of ANDA No. 204587.

61. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204587 seeking approval for the commercial marketing of Hetero Labs' generic ritonavir tablets before the expiration date of the '752 patent constitutes infringement of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

62. Hetero Labs' inducement of Hetero USA to file ANDA No. 204587 constitutes infringement under § 271(b).

63. On information and belief, under § 271(b), Hetero Labs has knowingly and actively induced and specifically intended the acts of Hetero USA that will constitute direct infringement upon approval of ANDA No. 204587.

64. On information and belief, under § 271(b), Hetero USA has knowingly and actively induced and specifically intended the acts of Hetero Labs that will constitute direct infringement upon approval of ANDA No. 204587.

65. Upon FDA approval of ANDA No. 204587, Hetero USA and Hetero Labs will each infringe one or more claims of the '752 patent, either literally or under the doctrine of equivalents, under § 271(a) by making, using, offering to sell, selling, and/or importing generic

ritonavir tablets, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 204587 shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity.

66. On information and belief, Hetero USA and Hetero Labs know and intend that physicians will prescribe and patients will take Hetero Labs' generic ritonavir tablets for which approval is sought in ANDA No. 204587, and therefore will infringe at least one claim in the '752 patent.

67. On information and belief, Hetero USA and Hetero Labs had knowledge of the '752 patent and, by its promotional activities and proposed package insert for Hetero Labs' generic ritonavir tablets, know or should know that it will aid and abet another's direct infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents.

68. On information and belief, Hetero USA and Hetero Labs are aware and/or have knowledge that healthcare professionals and/or patients will use their generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the '752 patent.

69. On information and belief, and in accordance with at least their proposed package insert, Hetero USA and Hetero Labs plan to make, use, sell, offer to sell, and/or import their ritonavir tablets for uses that will infringe the '752 patent. Hetero's ritonavir tablets are a material part of these infringing uses and have no substantial non-infringing uses.

70. The offering to sell, sale, and/or importation of generic ritonavir tablets would actively induce or contribute to infringement of at least one of the claims of the '752 patent,

either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of AbbVie's '752 patent, as evidenced by Hetero's March 29, 2013 Notice Letter.

71. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and actively inducing and contributing to infringement of at least one claim of the '752 patent. Pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

THIRD COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 8,268,349 B2

72. Paragraphs 1-71 are incorporated herein by reference.

73. On information and belief, Hetero USA, on behalf of Hetero Labs, filed ANDA No. 204587 in order to obtain approval to market generic ritonavir tablets in the United States before the expiration of the '349 patent. On information and belief, ANDA No. 204587 identifies Hetero Labs as the manufacturer of the generic ritonavir tablets. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '349 patent are purportedly invalid and/or not infringed.

74. On information and belief, Hetero USA and Hetero Labs acted in concert to seek FDA regulatory approval for generic ritonavir tablets manufactured by Hetero Labs. On information and belief, Hetero Labs actively and knowingly aided and abetted Hetero USA in the filing of ANDA No. 204587.

75. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204587 seeking approval for the commercial marketing of Hetero Labs' generic ritonavir tablets before the expiration date of the '349 patent constitutes infringement of one or more claims of the '349 patent, either literally or under the doctrine of equivalents.

76. Hetero Labs' inducement of Hetero USA to file ANDA No. 204587 constitutes infringement under § 271(b).

77. On information and belief, under § 271(b), Hetero Labs has knowingly and actively induced and specifically intended the acts of Hetero USA that will constitute direct infringement upon approval of ANDA No. 204587.

78. On information and belief, under § 271(b), Hetero USA has knowingly and actively induced and specifically intended the acts of Hetero Labs that will constitute direct infringement upon approval of ANDA No. 204587.

79. Upon FDA approval of ANDA No. 204587, Hetero USA and Hetero Labs will each infringe one or more claims of the '349 patent, either literally or under the doctrine of equivalents, under § 271(a) by making, using, offering to sell, selling, and/or importing generic ritonavir tablets, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 204587 shall be no earlier than the expiration date of the '349 patent and any additional periods of exclusivity.

80. On information and belief, Hetero USA and Hetero Labs are aware and/or have knowledge that healthcare professionals and/or patients will use their generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the '349 patent.

81. The offering to sell, sale, making, and/or importation of generic ritonavir tablets would actively induce infringement of at least one of the claims of the '349 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of AbbVie's '349 patent, as evidenced by Hetero's March 29, 2013 Notice Letter.

82. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '349 patent. Pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

FOURTH COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 6,037,157

83. Paragraphs 1-82 are incorporated herein by reference.

84. On information and belief, Hetero USA, on behalf of Hetero Labs, filed ANDA No. 204587 in order to obtain approval to market generic ritonavir tablets in the United States before the expiration of the '157 patent. On information and belief, ANDA No. 204587 identifies Hetero Labs as the manufacturer of the generic ritonavir tablets. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '157 patent are purportedly invalid and/or not infringed.

85. On information and belief, Hetero USA and Hetero Labs acted in concert to seek FDA regulatory approval for generic ritonavir tablets manufactured by Hetero Labs. On information and belief, Hetero Labs actively and knowingly aided and abetted Hetero USA in the filing of ANDA No. 204587.

86. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204587 seeking approval for the commercial marketing of Hetero Labs' generic ritonavir tablets before the expiration date of the '157 patent constitutes infringement of one or more claims of the '157 patent, either literally or under the doctrine of equivalents.

87. Hetero Labs' inducement of Hetero USA to file ANDA No. 204587 constitutes infringement under § 271(b).

88. On information and belief, under § 271(b), Hetero Labs has knowingly and actively induced and specifically intended the acts of Hetero USA that will constitute direct infringement upon approval of ANDA No. 204587.

89. On information and belief, under § 271(b), Hetero USA has knowingly and actively induced and specifically intended the acts of Hetero Labs that will constitute direct infringement upon approval of ANDA No. 204587.

90. Upon FDA approval of ANDA No. 204587, Hetero USA and Hetero Labs will each infringe one or more claims of the '157 patent, either literally or under the doctrine of equivalents, by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 204587 shall be no earlier than the expiration date of the '157 patent and any additional periods of exclusivity.

91. On information and belief, Hetero USA and Hetero Labs know and intend that physicians will prescribe and patients will take Hetero Labs' generic ritonavir tablets for which approval is sought in ANDA No. 204587, and therefore will infringe at least one claim in the '157 patent.

92. On information and belief, Hetero USA and Hetero Labs had knowledge of the '157 patent and, by its promotional activities and proposed package insert for Hetero Labs' generic ritonavir tablets, know or should know that it will aid and abet another's direct infringement of at least one of the claims of the '157 patent, either literally or under the doctrine of equivalents.

93. On information and belief, and in accordance with at least their proposed package insert, Hetero USA and Hetero Labs plan to make, use, sell, offer to sell, and/or import their

ritonavir tablets for uses that will infringe the ’157 patent. Hetero’s ritonavir tablets are a material part of these infringing uses and have no substantial non-infringing uses.

94. On information and belief, Hetero USA and Hetero Labs are aware and/or have knowledge that healthcare professionals and/or patients will use their generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the ’157 patent.

95. The offering to sell, sale, making, and/or importation of generic ritonavir tablets would actively induce infringement of at least one of the claims of the ’157 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of AbbVie’s ’157 patent, as evidenced by Hetero’s April 1, 2013 Notice Letter.

96. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the ’157 patent. Pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

FIFTH COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 6,703,403 B2

97. Paragraphs 1-96 are incorporated herein by reference.

98. On information and belief, Hetero USA, on behalf of Hetero Labs, filed ANDA No. 204587 in order to obtain approval to market generic ritonavir tablets in the United States before the expiration of the ’403 patent. On information and belief, ANDA No. 204587 identifies Hetero Labs as the manufacturer of the generic ritonavir tablets. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the ’403 patent are purportedly invalid and/or not infringed.

99. On information and belief, Hetero USA and Hetero Labs acted in concert to seek FDA regulatory approval for generic ritonavir tablets manufactured by Hetero Labs. On information and belief, Hetero Labs actively and knowingly aided and abetted Hetero USA in the filing of ANDA No. 204587.

100. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204587 seeking approval for the commercial marketing of Hetero Labs' generic ritonavir tablets before the expiration date of the '403 patent constitutes infringement of one or more claims of the '403 patent, either literally or under the doctrine of equivalents.

101. Hetero Labs' inducement of Hetero USA to file ANDA No. 204587 constitutes infringement under § 271(b).

102. On information and belief, under § 271(b), Hetero Labs has knowingly and actively induced and specifically intended the acts of Hetero USA that will constitute direct infringement upon approval of ANDA No. 204587.

103. On information and belief, under § 271(b), Hetero USA has knowingly and actively induced and specifically intended the acts of Hetero Labs that will constitute direct infringement upon approval of ANDA No. 204587.

104. Upon FDA approval of ANDA No. 204587, Hetero USA and Hetero Labs will each infringe one or more claims of the '403 patent, either literally or under the doctrine of equivalents, by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 204587 shall be no earlier than the expiration date of the '403 patent and any additional periods of exclusivity.

105. On information and belief, Hetero USA and Hetero Labs know and intend that physicians will prescribe and patients will take Hetero Labs' generic ritonavir tablets for which approval is sought in ANDA No. 204587, and therefore will infringe at least one claim in the '403 patent.

106. On information and belief, Hetero USA and Hetero Labs had knowledge of the '403 patent and, by its promotional activities and proposed package insert for Hetero Labs' generic ritonavir tablets, know or should know that it will aid and abet another's direct infringement of at least one of the claims of the '403 patent, either literally or under the doctrine of equivalents

107. On information and belief, and in accordance with at least their proposed package insert, Hetero USA and Hetero Labs plan to make, use, sell, offer to sell, and/or import their ritonavir tablets for uses that will infringe the '403 patent. Hetero's ritonavir tablets are a material part of these infringing uses and have no substantial non-infringing uses.

108. On information and belief, Hetero USA and Hetero Labs are aware and/or have knowledge that healthcare professionals and/or patients will use their generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the '403 patent.

109. The offering to sell, sale, making, and/or importation of generic ritonavir tablets would actively induce infringement of at least one of the claims of the '403 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of AbbVie's '403 patent, as evidenced by Hetero's April 1, 2013 Notice Letter.

110. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '403 patent. Pursuant to 35 U.S.C.

§ 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

SIXTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '359 PATENT

111. Paragraphs 1-110 are incorporated herein by reference.

112. On information and belief, Hetero is actively seeking approval to sell generic ritonavir tablets for the same indications and the same dosage and methods of use as the Norvir® product sold by AbbVie.

113. Upon further information and belief, Hetero intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

114. On information and belief, Hetero has knowledge of the '359 patent and will knowingly induce infringement of the '359 patent, if the FDA approves ANDA No. 204587 before the expiration of the '359 patent. On information and belief, if the FDA approves ANDA No. 204587, Hetero Labs will import into the United States generic ritonavir tablets, despite an objectively high likelihood that Hetero Labs' importation into the United States, and Hetero USA's marketing, offering for sale, and sale, of Hetero Labs' generic ritonavir tablets in the United States will constitute infringement of a valid patent. On information and belief, this risk is either known or should be known to Hetero USA.

115. On information and belief, Hetero Labs' generic ritonavir tablets, if approved by the FDA, will be imported by Hetero into the United States, and marketed, offered for sale, and sold in the United States by Hetero USA, which will constitute direct infringement of 35 U.S.C. § 271(a) of the '359 patent by Hetero Labs. On information and belief, that importation, marketing, offering for sale, and sale will occur with Hetero USA's specific intent and encouragement, and will be conduct that Hetero USA knows or should know will occur. On information and belief, Hetero USA will actively induce, encourage, aid, and abet that conduct,

with knowledge and specific intent that the conduct will be in contravention of the AbbVie's rights under the '359 patent.

116. If the FDA approves ANDA No. 204587, the import into the United States of generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sale in the United States before the expiration of the '359 patent will actively induce infringement by others under 35 U.S.C. § 271(b) by Hetero USA of one or more claims of the '359 patent, either literally or under the doctrine of equivalents.

117. Hetero's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '359 patent.

118. A case or controversy exists between AbbVie and Hetero regarding the infringement and validity of the '359 patent.

119. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Hetero having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Hetero's threatened infringement of the '359 patent.

120. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

SEVENTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '752 PATENT

121. Paragraphs 1-120 are incorporated herein by reference.

122. On information and belief, Hetero is actively seeking approval to sell generic ritonavir tablets for the same indications and the same dosage and methods of use as the Norvir® product sold by AbbVie.

123. Upon further information and belief, Hetero intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

124. On information and belief, Hetero has knowledge of the '752 patent and will knowingly induce infringement of the '752 patent, if the FDA approves ANDA No. 204587 before the expiration of the '752 patent. On information and belief, if the FDA approves ANDA No. 204587, Hetero Labs will import into the United States generic ritonavir tablets, despite an objectively high likelihood that Hetero Labs' importation into the United States, and Hetero USA's marketing, offering for sale, and sale, of Hetero Labs' generic ritonavir tablets in the United States will constitute infringement of a valid patent. On information and belief, this risk is either known or should be known to Hetero USA.

125. On information and belief, Hetero Labs' generic ritonavir tablets, if approved by the FDA, will be imported by Hetero into the United States, and marketed, offered for sale, and sold in the United States by Hetero USA, which will constitute direct infringement of 35 U.S.C. § 271(a) of the '752 patent by Hetero Labs. On information and belief, that importation, marketing, offering for sale, and sale will occur with Hetero USA's specific intent and encouragement, and will be conduct that Hetero USA knows or should know will occur. On information and belief, Hetero USA will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of the AbbVie's rights under the '752 patent.

126. If the FDA approves ANDA No. 204587, the import into the United States of generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sale in the United States before the expiration of the '752 patent will actively induce infringement by others under 35 U.S.C. § 271(b) and/or contribute to infringement under § 271(c) by Hetero USA of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

127. Hetero's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '752 patent.

128. A case or controversy exists between AbbVie and Hetero regarding the infringement and validity of the '752 patent.

129. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Hetero having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Hetero's threatened infringement of the '752 patent.

130. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

EIGHTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '349 PATENT

131. Paragraphs 1-130 are incorporated herein by reference.

132. On information and belief, Hetero is actively seeking approval to sell generic ritonavir tablets for the same indications and the same dosage and methods of use as the Norvir® product sold by AbbVie.

133. Upon further information and belief, Hetero intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

134. On information and belief, Hetero has knowledge of the '349 patent and will knowingly induce infringement of the '349 patent, if the FDA approves ANDA No. 204587 before the expiration of the '349 patent. On information and belief, if the FDA approves ANDA No. 204587, Hetero Labs will import into the United States generic ritonavir tablets, despite an objectively high likelihood that Hetero Labs' importation into the United States, and Hetero USA's marketing, offering for sale, and sale, of Hetero Labs' generic ritonavir tablets in the

United States will constitute infringement of a valid patent. On information and belief, this risk is either known or should be known to Hetero USA.

135. On information and belief, Hetero Labs' generic ritonavir tablets, if approved by the FDA, will be imported by Hetero into the United States, and marketed, offered for sale, and sold in the United States by Hetero USA, which will constitute direct infringement of 35 U.S.C. § 271(a) of the '349 patent by Hetero Labs. On information and belief, that importation, marketing, offering for sale, and sale will occur with Hetero USA's specific intent and encouragement, and will be conduct that Hetero USA knows or should know will occur. On information and belief, Hetero USA will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of the AbbVie's rights under the '349 patent.

136. If the FDA approves ANDA No. 204587, the import into the United States of generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sale in the United States before the expiration of the '349 patent will actively induce infringement by others under 35 U.S.C. § 271(b) by Hetero USA of one or more claims of the '349 patent, either literally or under the doctrine of equivalents.

137. Hetero's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '349 patent.

138. A case or controversy exists between AbbVie and Hetero regarding the infringement and validity of the '349 patent.

139. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Hetero having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Hetero's threatened infringement of the '349 patent.

140. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

NINTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '157 PATENT

141. Paragraphs 1-140 are incorporated herein by reference.

142. On information and belief, Hetero is actively seeking approval to sell generic ritonavir tablets for the same indications and the same dosage and methods of use as the Norvir® product sold by AbbVie.

143. Upon further information and belief, Hetero intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

144. On information and belief, Hetero has knowledge of the '157 patent and will knowingly induce infringement of the '157 patent, if the FDA approves ANDA No. 204587 before the expiration of the '157 patent. On information and belief, if the FDA approves ANDA No. 204587, Hetero Labs will import into the United States generic ritonavir tablets, despite an objectively high likelihood that Hetero Labs' importation into the United States, and Hetero USA's marketing, offering for sale, and sale, of Hetero Labs' generic ritonavir tablets in the United States will constitute infringement of a valid patent. On information and belief, this risk is either known or should be known to Hetero USA.

145. On information and belief, Hetero Labs' generic ritonavir tablets, if approved by the FDA, will be imported by Hetero into the United States, and marketed, offered for sale, and sold in the United States by Hetero USA, which will constitute direct infringement of 35 U.S.C. § 271(a) of the '157 patent by Hetero Labs. On information and belief, that importation, marketing, offering for sale, and sale will occur with Hetero USA's specific intent and encouragement, and will be conduct that Hetero USA knows or should know will occur. On

information and belief, Hetero USA will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of the AbbVie's rights under the '157 patent.

146. If the FDA approves ANDA No. 204587, the import into the United States of generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sale in the United States before the expiration of the '157 patent will actively induce infringement by others under 35 U.S.C. § 271(b) and/or contribute to infringement under § 271(c) by Hetero USA of one or more claims of the '157 patent, either literally or under the doctrine of equivalents.

147. Hetero's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '157 patent.

148. A case or controversy exists between AbbVie and Hetero regarding the infringement and validity of the '157 patent.

149. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Hetero having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Hetero's threatened infringement of the '157 patent.

150. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

TENTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '403 PATENT

151. Paragraphs 1-150 are incorporated herein by reference.

152. On information and belief, Hetero is actively seeking approval to sell generic ritonavir tablets for the same indications and the same dosage and methods of use as the Norvir® product sold by AbbVie.

153. Upon further information and belief, Hetero intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

154. On information and belief, Hetero has knowledge of the ’403 patent and will knowingly induce infringement of the ’403 patent, if the FDA approves ANDA No. 204587 before the expiration of the ’403 patent. On information and belief, if the FDA approves ANDA No. 204587, Hetero Labs will import into the United States generic ritonavir tablets, despite an objectively high likelihood that Hetero Labs’ importation into the United States, and Hetero USA’s marketing, offering for sale, and sale, of Hetero Labs’ generic ritonavir tablets in the United States will constitute infringement of a valid patent. On information and belief, this risk is either known or should be known to Hetero USA.

155. On information and belief, Hetero Labs’ generic ritonavir tablets, if approved by the FDA, will be imported by Hetero into the United States, and marketed, offered for sale, and sold in the United States by Hetero USA, which will constitute direct infringement of 35 U.S.C. § 271(a) of the ’403 patent by Hetero Labs. On information and belief, that importation, marketing, offering for sale, and sale will occur with Hetero USA’s specific intent and encouragement, and will be conduct that Hetero USA knows or should know will occur. On information and belief, Hetero USA will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of the AbbVie’s rights under the ’403 patent.

156. If the FDA approves ANDA No. 204587, the import into the United States of generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sale in the United States before the expiration of the ’403 patent will actively induce infringement by others

under 35 U.S.C. § 271(b) and/or contribute to infringement under § 271(c) by Hetero USA of one or more claims of the ’403 patent, either literally or under the doctrine of equivalents.

157. Hetero’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the ’403 patent.

158. A case or controversy exists between AbbVie and Hetero regarding the infringement and validity of the ’403 patent.

159. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Hetero having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Hetero’s threatened infringement of the ’403 patent.

160. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that this Court enter judgment in its favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero USA’s submission to the FDA of ANDA No. 204587 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs’ generic ritonavir tablets before the expiration of the ’359 patent was an act of infringement of the ’359 patent;

(2) declaring that Hetero Labs’ commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of generic ritonavir tablets would constitute infringement of the ’359 patent;

(3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 204587 to obtain approval for the sale and import of the generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sell in the United States before the expiration of the '359 patent were acts of infringement of one or more claims of the '359 patent;

(4) declaring that Hetero would infringe one or more claims of the '359 patent under one or more of 35 U.S.C. §§ 271(a)-(b) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Hetero Labs' generic ritonavir tablets prior to expiration of the '359 patent and any additional dates of exclusivity therefor;

(5) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero USA's submission to the FDA of ANDA No. 204587 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs' generic ritonavir tablets before the expiration of the '752 patent was an act of infringement of the '752 patent;

(6) declaring that Hetero Labs' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of generic ritonavir tablets would constitute infringement of the '752 patent;

(7) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 204587 to obtain approval for the sale and import of the generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sell in the United States before the expiration of the '752 patent were acts of infringement of one or more claims of the '752 patent;

(8) declaring that Hetero would infringe one or more claims of the '752 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offering to sell, and sale

in, and importation into the United States of Hetero Labs' generic ritonavir tablets prior to expiration of the '752 patent and any additional dates of exclusivity therefor;

(9) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero USA's submission to the FDA of ANDA No. 204587 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs' generic ritonavir tablets before the expiration of the '349 patent was an act of infringement of the '349 patent;

(10) declaring that Hetero Labs' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of generic ritonavir tablets would constitute infringement of the '349 patent;

(11) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 204587 to obtain approval for the sale and import of the generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sell in the United States before the expiration of the '349 patent were acts of infringement of one or more claims of the '349 patent;

(12) declaring that Hetero would infringe one or more claims of the '349 patent under one or more of 35 U.S.C. §§ 271(a)-(b) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Hetero Labs' generic ritonavir tablets prior to expiration of the '349 patent and any additional dates of exclusivity therefor;

(13) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero USA's submission to the FDA of ANDA No. 204587 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs' generic ritonavir tablets before the expiration of the '157 patent was an act of infringement of the '157 patent;

(14) declaring that Hetero Labs' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs' generic ritonavir tablets would constitute infringement of the '157 patent;

(15) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 204587 to obtain approval for the sale and import of the generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sell in the United States before the expiration of the '157 patent were acts of infringement of one or more claims of the '157 patent;

(16) declaring that Hetero would infringe one or more claims of the '157 patent under one or more of 35 U.S.C. §§ 271(b)-(c) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Hetero Labs' generic ritonavir tablets prior to expiration of the '157 patent and any additional dates of exclusivity therefor;

(17) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero USA's submission to the FDA of ANDA No. 204587 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs' generic ritonavir tablets before the expiration of the '403 patent was an act of infringement of the '403 patent;

(18) declaring that Hetero Labs' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs' generic ritonavir tablets would constitute infringement of the '403 patent;

(19) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 204587 to obtain approval for the sale and import of the generic ritonavir tablets by Hetero Labs for Hetero USA

to market, offer for sale, and sell in the United States before the expiration of the ’403 patent were acts of infringement of one or more claims of the ’403 patent;

(20) declaring that Hetero would infringe one or more claims of the ’403 patent under one or more of 35 U.S.C. §§ 271(b)-(c) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Hetero Labs’ generic ritonavir tablets prior to expiration of the ’403 patent and any additional dates of exclusivity therefor;

(21) ordering that the effective date of any FDA approval of Hetero Labs’ generic ritonavir tablets shall be no earlier than the expiration date of the ’359 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(22) ordering that the effective date of any FDA approval of Hetero Labs’ generic ritonavir tablets shall be no earlier than the expiration date of the ’752 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(23) ordering that the effective date of any FDA approval of Hetero Labs’ generic ritonavir tablets shall be no earlier than the expiration date of the ’349 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(24) ordering that the effective date of any FDA approval of Hetero Labs’ generic ritonavir tablets shall be no earlier than the expiration date of the ’157 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(25) ordering that the effective date of any FDA approval of Hetero Labs’ generic ritonavir tablets shall be no earlier than the expiration date of the ’403 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(26) enjoining Hetero Labs and all persons acting in concert with Hetero Labs, from commercially manufacturing, using, offering for sale, or selling Hetero Labs’ generic ritonavir

tablets within the United States or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '359 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(27) enjoining Hetero Labs and all persons acting in concert with Hetero Labs, from commercially manufacturing, using, offering for sale, or selling Hetero Labs' generic ritonavir tablets within the United States or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '752 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(28) enjoining Hetero Labs and all persons acting in concert with Hetero Labs, from commercially manufacturing, using, offering for sale, or selling Hetero Labs' generic ritonavir tablets within the United States or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '349 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(29) enjoining Hetero Labs and all persons acting in concert with Hetero Labs, from commercially manufacturing, using, offering for sale, or selling Hetero Labs' generic ritonavir tablets within the United States or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '157 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(30) enjoining Hetero Labs and all persons acting in concert with Hetero Labs, from commercially manufacturing, using, offering for sale, or selling Hetero Labs' generic ritonavir tablets within the United States or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '403 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B)

(31) enjoining Hetero USA and all persons acting in concert with Hetero USA, from commercially manufacturing, using, offering for sale, or selling or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '359 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(32) enjoining Hetero USA and all persons acting in concert with Hetero USA, from commercially manufacturing, using, offering for sale, or selling or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '752 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(33) enjoining Hetero USA and all persons acting in concert with Hetero USA, from commercially manufacturing, using, offering for sale, or selling or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '349 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(34) enjoining Hetero USA and all persons acting in concert with Hetero USA, from commercially manufacturing, using, offering for sale, or selling or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '157 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(35) enjoining Hetero USA and all persons acting in concert with Hetero USA, from commercially manufacturing, using, offering for sale, or selling or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '403 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(36) enjoining Hetero and all persons acting in concert with Hetero, from seeking, obtaining, or maintaining approval of ANDA No. 204587 until the expiration of the '359 patent, and any additional periods of exclusivity;

(37) enjoining Hetero and all persons acting in concert with Hetero, from seeking, obtaining, or maintaining approval of ANDA No. 204587 until the expiration of the '752 patent, and any additional periods of exclusivity;

(38) enjoining Hetero and all persons acting in concert with Hetero, from seeking, obtaining, or maintaining approval of ANDA No. 204587 until the expiration of the '349 patent, and any additional periods of exclusivity;

(39) enjoining Hetero and all persons acting in concert with Hetero, from seeking, obtaining, or maintaining approval of ANDA No. 204587 until the expiration of the '157 patent, and any additional periods of exclusivity;

(40) enjoining Hetero and all persons acting in concert with Hetero, from seeking, obtaining, or maintaining approval of ANDA No. 204587 until the expiration of the '403 patent, and any additional periods of exclusivity;

(41) declaring this to be an exceptional case and awarding AbbVie its attorney fees under 35 U.S.C. § 285;

(42) declaring the '359 patent valid and enforceable;

(43) declaring the '752 patent valid and enforceable;

(44) declaring the '349 patent valid and enforceable;

(45) declaring the '157 patent valid and enforceable;

(46) declaring the '403 patent valid and enforceable;

(47) awarding AbbVie its costs and expenses in this action; and

(48) awarding AbbVie any further and additional relief as this Court deems just and proper.

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/s/ Mary B. Graham

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